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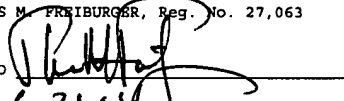
In re Patent Application of ) Examiner: Kathryn Odland  
Harry J. Buncke ) Group Art Unit: 3743  
Serial No.09/596,806 ) File No.: 540P  
Filed: June 19, 2000 )  
For: SURGICAL CLIP APPLIER ) Tiburon, California  
WITH REMOTE OPERATION )  
Hon. Commissioner for Patents  
P.O. Box 1450  
Alexandria, Virginia 22313

I HEREBY CERTIFY THAT THIS CORRESPONDENCE IS BEING DEPOSITED WITH THE UNITED STATES POSTAL SERVICE "EXPRESS MAIL POST OFFICE TO ADDRESSEE" SERVICE UNDER 37 CFR 1.10 ON THE DATE INDICATED ABOVE AND IS ADDRESSED TO: COMMISSIONER FOR PATENTS, P.O. BOX 1450, ALEXANDRIA, VIRGINIA 22313.

THOMAS M. FREIBURGER, Reg. No. 27,063

SIGNED

DATE

  
6-21-04

Dear Sir:

**BRIEF ON APPEAL**

This is an appeal of the examiner's final rejection of the claims, dated January 13, 2004. A Notice of Appeal was filed April 21, 2004, along with a request for a one month extension of time. This brief is filed in triplicate, along with the brief fee of \$165.00.

**REAL PARTY IN INTEREST**

The real party in interest in this appeal is Harry J. Buncke, the inventor/applicant.

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### RELATED APPEALS AND INTERFERENCES

None is pending.

### STATUS OF CLAIMS

No claim is canceled herewith. The claims remaining in the application are claims 1-11. No claim was indicated by the examiner in the final action to be allowable.

### STATUS OF AMENDMENT

No amendments were made after final rejection. An amendment after final was proposed but not entered.

### SUMMARY OF THE INVENTION

The invention concerns a surgeon's staple applying device, particularly for microsurgery. With the invention, the difficulty of holding a clip applier (a typical prior art clip applier) very steadily under the microscope to apply a clip to attach tissue is overcome by the use of a flexible cable or fluid-carrying tubing attached to the handle of the clip applier enabling the requisite force to be applied remotely and indirectly without causing any motion at the point of and at the instant of clip application. In other words, the actuation of the device is prevented from and isolated from jarring or shaking the clip applier tip.

The invention applies to surgical clip devices where the clips are applied from the end of an extending stem by movement of an internal member within the handle of the clip applier, so as to cause movement of a clip applying component in the stem of the device, which deploys, crimps and applies a clip. The drawings show a typical prior art clip applier of a type to which this invention would apply, in Figures 1-4. Such a clip applier has an elongated stem with the clip applied from the end of the stem, and a pair of "wings" or arms which are set directly on the handle of the device, for the surgeon to squeeze to apply a clip. Movement at the instant of clip application, induced by the surgeon's hand, is almost inevitable with this type of clip applier. The movement is multiplied by the lengthy stem. The problem is that the surgeon must squeeze the actuator handle to apply a clip, thereby moving the device or causing a slight trembling of the hand under such muscle contraction, which moves the tip even more. The applicant, a microsurgeon of renown, has observed this many times.

In a preferred embodiment a device of the invention includes a hand held clip applier having a handle which is gripped by the user, and a flexible cable release or hydraulic actuator or other very flexible remotely-actuated device for delivering an actuating force to an internal moveable member of the clip applier without applying the actuating force directly to the

hand-held clip applier, thus isolating any vibration or unsteady hand movement from the clip applier tip.

In one preferred embodiment, the clip applier is capable of applying clips to blood vessels 2 mm and under, and this clip applier may be a well known construction such as the product Auto Suture VCS, with the modification which is the subject of the invention. This prior art clip applier is the device generally shown in Figures 1-4 of the drawings. Such a clip applier has a moveable member in the handle which, when caused to move by a force applied from outside the handle in accordance with the invention, is effective to cause movement of the clip applying component in the stem so as to cause dispensing and application of a clip. Further, a linkage of appropriate form preferably is included within the handle, engaged with the moveable member in the handle and extending to a position so as to be capable of receiving a force from the exterior of the handle. The moveable member and the linkage means can be one piece if desired.

The flexible actuator, which may be in the form of a flexible cable release device, or a hydraulic or pneumatic tube, has a cable sheath or tube with an internal force-applying medium capable of delivering a force through the sheath or tube, and having a remote actuator at a remote end of the flexible device, remote from the clip applier, for applying a force to slide the moveable member through the sheath so as to cause movement of a

component at a proximal (i.e. at the handle) end of the tubular sheath when the remote actuator is engaged.

It is important to note that the flexible cable release or remote force-transmitting device serves to isolate the handle, which is held by the surgeon and which is fixed to the tip that applies the clips, from the hand, foot or other instrument that is used to apply the force at the remote end of the flexible cable. The flexible cable is not simply something that can be bent or manipulated, it is defined as being sufficiently flexible as to avoid movement of the clip applier's tip when the remote actuator is engaged and moved to apply the force. This prevents any effect on the accuracy of clip application, by the force that is used to deploy a clip. The force can be applied by a different person than the surgeon holding the handle of the clip applier, or it could be applied by the other hand of the surgeon or by a foot of the surgeon or an assistant. The invention not only prevents such movement but also allows for use of a clip applier (e.g. of the type shown in Figures 1-4) in narrow, difficult positions where a surgeon would be unable to squeeze the wings or arms of the prior art clip applier because of the narrow surroundings. With the invention the surgeon can hold the handle near its base end when needed rather than at the position of the prior art wings, to position the tip of the clip applier in such a narrow cavity while the deploying force is applied at

the remote end of the isolating flexible cable.

### ISSUES

Issues on appeal are:

(a) Whether apparatus claims 1-8 define subject matter which would have been obvious over the admitted prior art (e.g. the device of Figures 1-4) in view of Swiggett U.S. Patent No. 4,485,817, as set forth in the examiner's final action.

(b) Whether method claims 9-11 would be obvious for the same reasons given by the examiner relative to the apparatus claims.

### GROUPING OF CLAIMS

The method claims are different in scope from the apparatus claims and do not stand or fall with the method claims.

Moreover, independent apparatus claims 1 and 3 differ in scope, claim 1 specifying a cable release device, and these two independent claims do not stand or fall together. Still further, no dependent claim under claim 1 is of precisely the same scope as any dependent claim under claim 3, and thus no claims stand or fall together.

### ARGUMENT

No two claims stand or fall together. The argument immediately above is incorporated herein by reference.

The § 103 Rejection of Claims 1-8:

In a lengthy rejection in paragraph 3 of the final action, the examiner essentially repeated all of the wording of the claims and pointed out that much of the content of the main claims is found in the admitted prior art, which it is. The examiner then recited the claim wording regarding the flexible force-transmitting or cable release device as what is lacking in the admitted prior art. This is at pages 3-5 of the final action.

The examiner then went on to say that the Swiggett reference, also a surgical clip applier, teaches all of the features that are missing in the admitted prior art. In doing this at pages 5-7 of the action, the examiner glosses over several of the important limitations of the claims, merely stating that Swiggett shows the same thing.

Basically, the entire weight of the examiner's argument hangs on the premise that the Swiggett device could be considered to have a handle at the clip-applying end of the device, i.e. presumably portion 34 of the applicator end 16 in Swiggett. This argument fails, for quite a few reasons.

Swiggett is an obvious reference and not a §102 anticipation reference. Thus, its teaching, as well as the disclosed structure, is important in this analysis. Swiggett teaches a device for applying clips, as does the applicant, but for a

different purpose. The reference does not seek to avoid movement induced by the surgeon's hand, translated through the length of the device to the clip applying tip. Rather, the reference teaches a bendable (but stiff) configuration-retaining extension, leading to the tip where the clips are applied. The purpose is to enable bending of this extension as desired by the user, to enter cavities or lumens of the body, as well as to provide angular positioning of the tip. Figure 1 of the Swiggett drawings indicates a lumen of the body which could be the colon, in dashed lines at 22 and 24. The applicator end of the device is adapted to clamp two portions of the lumen and hold them while a clip is applied, by squeezing the handle 30 at the surgeon end of the apparatus. Nothing in the reference discloses or suggests a goal of isolating the surgeon's hand movement in squeezing the actuator 30 from the applicator end where the clips are applied, and nothing in the reference suggests structure for such purpose. Such isolation or immobilization probably is not needed pursuant to the purpose of Swiggett's device, which is shown as fitting closely within a body lumen. Because of these facts, it seems preposterous to claim that any portion of the applicator end 16 in Swiggett is a "handle" as defined in the current claims. In the suggested use of Swiggett's tool, that applicator end is buried within a lumen of the patient, possibly deep within the colon.



There are other specific assumptions of the examiner which are clearly wrong. She states that the "cable sheath and internal bracket are sufficiently flexible so as to avoid movement of the tip when the hand operable actuator is moved to apply the pushing force", p. 6, l. 1-3. This is manifestly not the case. Swiggett discloses an extension that is bendable, but stiff. The flexible shaft in the reference is sometimes described as flexible enough to bend during insertion into a body channel to conform to the configuration of the body channel, but it is also characterized as capable of retaining such a bent configuration during actuation. At column 2, lines 20 et seq. Swiggett says "The shaft is longitudinally flexible in any direction, and once bent into a given shape, will retain that shape." This is not what is defined in the current claims; the flexibility defined in the claims essentially recites a flimsy flexible force-transmitting device, one which will not affect the tip of the clip applier when force is applied to the remote end of the flexible cable or tube. This cannot be said about an extension shaft which presumably is bendable in the manner of a pipe cleaner.

The examiner argues, near the top of page 6 of the action, that the "applier can be held very steady in one hand with its tip under the microscope while the force to apply is supplied at the remote end of the cable release device, avoiding any movement

of the tip at the instant of the clip application." Yes, it is possible that the applicator end of Swiggett's device could be held in one hand of the surgeon, but this is not what is taught in Swiggett and it is contrary to the purpose of Swiggett. Moreover, this would not "avoid any movement of the tip at the instant of the clip application", because of the stiff shaft described by Swiggett ("once bent into a given shape, will retain that shape").

The "handle" of the Swiggett device is specifically defined, contrary to the assumptions in the examiner's arguments. At column 2, lines 14 et seq., the patent states "an instrument for applying surgical fasteners comprises an actuator (handle section), an applicator section . . .". The actuator is the actuator 12 shown in Figure 1, which is held in the hand of the surgeon. It is this that is defined as the "handle" in Swiggett. The far end of the device, i.e. the applicator 16, is not defined as a handle and is described as useful in extending far up into a lumen of a human organ. Nowhere is any suggestion to grip that working end.

Moreover, column 1 of the patent describes prior art of the type to which Swiggett's invention relates, stating:

"There are several known types of surgical staplers in which the stapling function takes place at a location which is relatively remote from the location at which the stapler is held and actuated by the operator [emphasis supplied]."

This certainly underscores that Swiggett's invention is another such surgical stapler where the stapling function takes place at the end of a device relatively remote from the place where the stapler is held and actuated by the operator, and this understanding is entirely commensurate with the entire disclosure and drawings.

It is an impermissible stretch for the examiner to assume that the stapling end in the Swiggett device, typically immersed deeply into an organ, constitutes a "handle" within the meaning of the present claims.

Another point relates to the stiffness of the extension or "shaft" in Swiggett. This shaft is stiff enough to retain its shape after being bent to a desired shape, for reasons commensurate with the purpose of Swiggett's invention. Note that there would be no reason for such stiffness if the remote end were to be held in the hand. Note also that the only non-sliding portion in the applicator end 16 of Swiggett apparently is the sleeve 34. That sleeve is relatively much smaller than the actuator handle 12, and apparently would have to be held between two fingers, again indicating that it is not a handle. Again, what is taught is important.

It thus seems manifest that the examiner has gone far beyond the maxim of interpreting the claims as broadly as reasonably possible, when maintaining that Swiggett teaches a "handle"

meeting the definition of such a handle in these patent claims (as they must be understood with reference to the present specification), located at Swiggett's applicator end which in preferred usage as taught by Swiggett will be half way up a patient's channel in an organ such as a colon. This simply makes no sense when one reads and appreciates the entire Swiggett disclosure.

Again it is pointed out that Swiggett is an obviousness reference in the examiner's rejection, not an anticipation reference. Thus, it is important that Swiggett did not teach a structure as called for in the current apparatus claims — Swiggett does not teach that the far end of the tool, i.e. the applicator end which is to be used inside a lumen of an organ, is to be used as a handle; thus, it does not teach structure which is a handle at that working end. The examiner's final rejection in some ways reads as if she is trying to make an anticipation rejection, yet she is not.<sup>1</sup>

Motivation to combine Swiggett and the acknowledged prior is lacking, not found in any of the prior art. Even if motivation were present, the supposed combination would not produce the

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<sup>1</sup> In a March 31, 2004 interview with the examiner and her S.P.E., Henry Bennett, the S.P.E. indicated all the claims would be allowable if the applicant submitted an amendment which literally distinguished the claimed hardware from Swiggett. The applicant submitted an after-final proposed amendment (which was not actually needed to distinguish from Swiggett in the opinion of the attorney), but the examiner refused entry of that amendment.

claimed invention.

The above discussion applies to both claims 1 and 3, although claim 1 is more specific than claim 3 in that it recites a flexible cable release device that includes a cable sheath and an internal cable that delivers a compressive pushing force, and including a pusher tail piece that extends out of a proximal end of a cable sheath when the hand operable actuator is engaged.

Claims 4-8 depend from claim 3 and provide further distinctions from the prior art. Claim 4 adds a threaded fitting between the flexible device and the handle, providing for removability. The examiner summarily dismisses this claim at the top of page 7, as reciting structure shown in Swiggett, but this is not the case, even though Swiggett shows some internal threads.

Claim 5 adds to claim 4 that the flexible device is a cable release device, with the actuator comprising a thumb button. This is more specific than claim 1, because it brings in the subjection matter of claim 3 and recites the thumb button.

Claim 6 adds to claim 3 that the remote flexible force-transmitting device is a hydraulic line with a liquid inside, and with a piston and cylinder as actuator. A second piston and cylinder are recited at the "proximal" end of the flexible device, i.e. at the tail end of a handle (terms such as "proximal" are used somewhat differently from Swiggett).

Swiggett also shows hydraulic actuation but not in the context of a very flexible cable designed and structured to prevent any actuator hand force from causing movement of an applicator end of a staple applying device. Claim 7 adds further to claim 6 that the actuator is a thumb button at the remote end of the flexible device. Claim 8 adds to claim 3 that the handle is round (as shown for example in Figure 9 of the current drawings) for comfortable gripping in any orientation. Although Swiggett shows any handle 12 which has round components, it includes the actuator handle 30 which does not meet the language of claim 8 as to orientation, and, as in claims 3, the actuator is not mounted on the handle, but is at a remote location behind it, separated by a very flexible force-transmitting device.

The § 103 Rejection of Claims 9-11:

The examiner goes very far afield at page 7 where she states that the method (of claims 9-11) would be obvious as in the apparatus rejection. This summary dismissal plainly ignores the fact that Swiggett teaches no method even resembling the method described in claims 9-11. Note that claim 9 requires the step of effecting the dispensing and application of a clip at the site to be closed by engaging the remote actuator at the remote end of the flexible device, with the engaging of the actuator not being performed by the hand holding the handle of the clip applier.

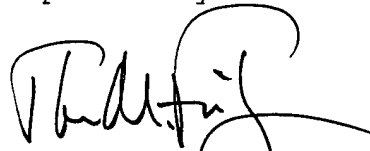
There are many serious flaws in the examiner's arguments regarding these claims, but this is the worst of them. The examiner first argues by flawed reasoning that Swiggett shows or suggests the structure of the invention, in part by showing a handle at the far end or applicator end of this device, then simply says that the method would be obvious because the apparatus is obvious. She clearly is pulling herself up by her bootstraps here, with an impossible leap on top of a flawed argument; she appears not to have read claim 9, not to have read the attorney's arguments, and not to have compared claim 9 to the prior art. If her position on claim 9 is that Swiggett is capable of such use (which she does not argue in the rejection), claim 9 is method claim and Swiggett very obviously does not teach or in any way suggest or indicate the possibility of such use. Swiggett teaches a modification of a stapler of a known type in which stapling takes place at a location relatively remote from the location at which the stapler is held and actuated by the operator. See column 1, lines 16 *et seq.* Swiggett's improvement was a bendable extension between the actuator and the staple applicator, stiff enough that any bend put into the extension will remain. 100% of Swiggett's disclosure relates to gripping of the Swiggett device at the handle or actuator 12, and only at that location. The tool structure recited in claim 9 was not known before, but even if it

were, or even if it were obvious, an unobvious method of using even a well-known prior tool is patentable. There is no question that claim 9 and its dependent claims are patentable.

CONCLUSION

It is therefore submitted that claims 1-11 are patentable over the prior art and should be allowed. The final rejection of the examiner should be overturned.

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'T. Freiburger', with a large, stylized loop at the end.

Date: June 21, 2004

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## APPENDIX

### CLAIMS ON APPEAL

1. A device for applying non-penetrating clips to small blood vessels or other wound sites or tissue separation sites where suturing or other wound closure techniques would be impossible or undesirable, comprising:

a hand-held clip applier, including:

a handle suitable for gripping in the hand of a surgeon,

a clip storing and dispensing stem extending from a forward end of the handle, the stem having a tip at a remote end, the tip including means for dispensing and serially applying metal clips in non-penetrating engaging configuration against sections of tissue on either side of a wound or tissue separation to clamp the two sections of tissue together, upon the receipt of mechanical force to a clip-applying component of the stem,

a movable member within the handle which, when caused to move by a force applied from outside the handle, is effective to cause movement of the clip-applying component in the stem so as to cause dispensing and application of a clip, and

linkage means engaged with the movable member within the handle and extending to a position in the handle capable of receiving a pushing force from the exterior of the handle, and

a flexible cable release device comprising a cable sheath, and an internal cable capable of delivering a compressive pushing force through the sheath, a hand operable actuator at a remote hand-grippable end of the cable release, remote from the clip applier, for applying a pushing force to slide the cable through sheath so as to cause extension of a pusher tailpiece out of a proximal end of the cable sheath when the hand operable actuator is engaged, the sheath at the proximal end having means for connection to the handle of the hand-held clip applier in a position to apply force to the linkage means in the handle by motion of the pusher tailpiece, thus advancing the linkage means and movable member within the handle, and thus advancing the clip-applying component to dispense and apply a clip when the thumb button on the flexible cable release device is pushed, the cable sheath and internal cable being sufficiently flexible as to avoid movement of the tip when the hand operable actuator is moved to apply said pushing force,

whereby with the cable release device connected to the clip applier the hand-held clip applier can be held very steadily in one hand with its tip under the microscope while the force to

apply a clip is supplied at the remote end of the cable release device, avoiding any movement of the tip at the instant of clip application.

2. The device of claim 1, wherein the handle is round so as to be capable of comfortable hand gripping in any rotational orientation.

3. A device for applying non-penetrating clips to blood vessels or other wound sites or tissue separation sites where suturing or other wound closure techniques would be impossible or undesirable, comprising:

a hand-held clip applier, including:

a handle suitable for gripping in the hand of a surgeon,

a clip storing and dispensing stem extending from a forward end of the handle, the stem having a tip at a remote end, the tip including means for dispensing and serially applying metal clips in non-penetrating engaging configuration against sections of tissue on either side of a wound or tissue separation to clamp the two sections of tissue together, upon the receipt of force to a clip-applying component of the stem,

a movable member within the handle which, when caused

to move by a force applied from outside the handle, is effective to cause movement of the clip-applying component in the stem so as to cause dispensing and application of a clip, and

linkage means adjacent to the movable member within the handle and extending to a position in the handle capable of receiving a force from the exterior of the handle, and a flexible remote force-transmitting device comprising a tubular sheath, and an internal movable medium capable of delivering a force through the tubular sheath, a remote actuator at a remote end of the flexible device, remote from the clip applier, for applying a force to slide the movable medium through the sheath so as to cause movement of a tailpiece at a proximal end of the tubular sheath when the remote actuator is engaged, the sheath at the proximal end being connected to the handle of the hand-held clip applier in a position to apply force to the linkage means in the handle by motion of the tailpiece, thus moving the linkage means and movable member within the handle, and thus advancing the clip-applying component to dispense and apply a clip when the remote actuator on the flexible force-transmitting device is engaged, the tubular sheath and medium being sufficiently flexible as to avoid movement of the tip when the remote actuator is engaged and moved to apply said force, whereby with the remote flexible force-transmitting device

connected to the clip applier the hand-held clip applier can be held very steadily in one hand, and can be gripped at any location desired along the length of the handle, while the force to apply a clip is supplied at the remote end of the flexible device, avoiding any movement of the tip at the instant of clip application.

4. The device of claim 3, wherein the remote flexible force-transmitting device has a threaded fitting at its proximal end, the tail end of the handle of the clip applier having a mating thread so that the flexible device is removable from the clip applier.

5. The device of claim 4, wherein the flexible force-transmitting device comprises a cable release device, said movable medium comprising an internal cable in the tubular sheath and the actuator comprising a thumb button.

6. The device of claim 3, wherein the remote flexible force-transmitting device comprises a hydraulic line containing liquid as said movable medium, and wherein the remote end of the flexible device has a piston and cylinder connected to put pressure on the liquid when the actuator is depressed, to force the liquid through the hydraulic tube, and said proximal end of

the flexible device having a second piston and cylinder with the piston connected to said tail piece, so that the linkage means and movable member are moved hydraulically when the actuator is depressed.

7. The device of claim 6, wherein the actuator comprises a thumb button connected to the piston at the remote end of the flexible device.

8. The device of claim 3, wherein the handle is round so as to be capable of comfortable hand gripping in any rotational orientation.

9. A method for applying non-penetrating surgical clips to blood vessels or other wound sites or tissue separation sites where suturing or other wound closure techniques would be difficult, awkward or undesirable, comprising:

providing a hand-held clip applier which includes:

a handle suitable for gripping in the hand of a surgeon,

a clip storing and dispensing stem extending from a forward end of the handle, the stem having a tip at a remote end, the tip including means for dispensing and serially applying metal clips in non-penetrating engaging

configuration against sections of tissue on either side of a wound or tissue separation to clamp the two sections of tissue together, upon the receipt of force to a clip-applying component of the stem,

a movable member within the handle which, when caused to move by a force applied from outside the handle, is effective to cause movement of the clip-applying component in the stem so as to cause dispensing and application of a clip, and

linkage means adjacent to the movable member within the handle and extending to a position in the handle capable of receiving a force from the exterior of the handle, and providing a flexible remote force-transmitting device connected to the handle of the clip applier, the force-transmitting device comprising a tubular sheath, and an internal movable medium capable of delivering a force through the tubular sheath, a remote actuator at a remote end of the flexible device, for applying a force to slide the movable medium through the sheath so as to cause movement of a tailpiece at a proximal end of the tubular sheath when the actuator is engaged, the sheath at the proximal end being connected to the handle of the hand-held clip applier in a position to apply force to the linkage means in the handle by motion of the tailpiece, thus moving the linkage means and movable member within the handle, and thus advancing

the clip-applying component to dispense and apply a clip when the actuator on the flexible force-transmitting device is engaged,

positioning the tip of the clip applier in an appropriate position to connect tissue, and

effecting dispensing and application of a clip at the site to be closed by engaging the remote actuator at the remote end of the flexible device, the engaging of the actuator not being performed by the hand holding the handle of the clip applier.

10. The method of claim 9, wherein the actuator is engaged by a person other than the person holding the handle of the clip applier.

11. The method of claim 9, wherein the actuator comprises a foot pedal and is depressed by the person holding the clip applier.